



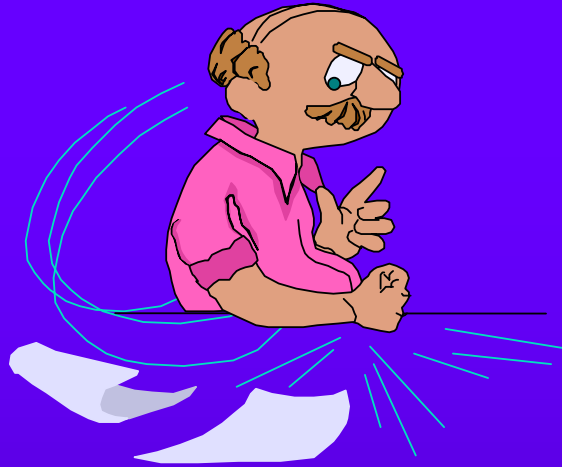
Errors in Laboratory Medicine

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University-Hospital of Padova, Italy

To err is human:

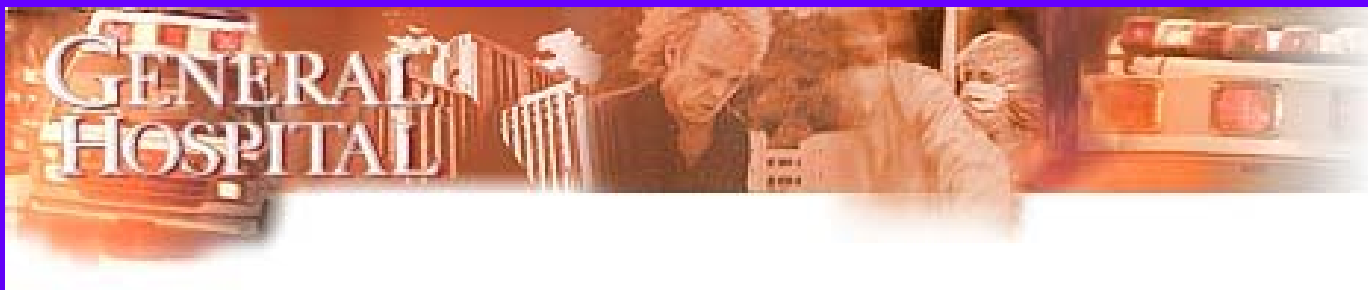


***building a safer
health system***

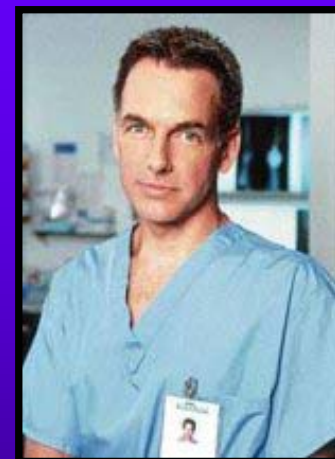


Kohn L.T., Corrigan J.M., Donaldson M.S., Eds. 1999

What About Us?



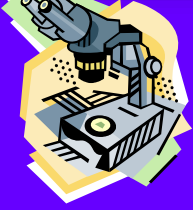
- ◆ Risk of death from avoidable injury
 - 2,917 per 1,000,000





LESSONS from the IOM REPORT

- ◆ The number of deaths that are reportedly due to medical errors is disturbingly high.
- ◆ The IOM report suggests that more Americans are ***killed in US hospital every 6 months than died in the entire Vietnam War.***
- ◆ If true, the healthcare system is a public health menace of epidemic proportions.

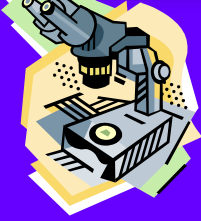


ERRORS IN MEDICINE:

WHAT ABOUT LABORATORY MEDICINE?

- ◆ There is a **shortage of scientific evidence** for documenting the types of laboratory errors and their frequency, and few studies consider the clinical impact of **laboratory errors** on medical and economic outcomes.

Plebani M, Bonini P. BMJ 2002; 324: 423-



ERRORS IN MEDICINE:

WHAT ABOUT LABORATORY MEDICINE?

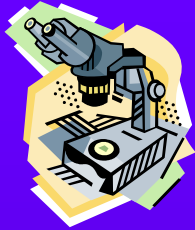
- ◆ The literature on errors in laboratory medicine is scarce, both for the insufficient attention paid to the problem, and for **practical difficulties** in reporting and measuring the number of errors.

Bonini P, Plebani M, Ceriotti F, Rubboli F

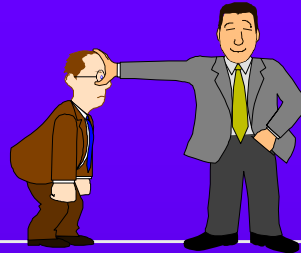
Clin Chem 2002; 48: 691-6



ERRORS IN LABORATORY MEDICINE



ACTUAL LIMITATIONS

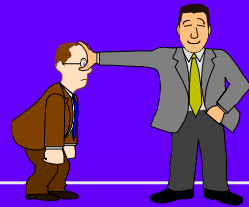


- ◆ Study design.
- ◆ Errors in laboratory or errors in laboratory medicine?
- ◆ Difficulties in identifying all types of errors.
- ◆ Lack or changing of Gold standards.

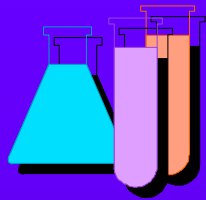
ERRORS IN LABORATORY MEDICINE:



ACTUAL LIMITATIONS (1)



- ◆ Most of the studies ***focus simply on analytical errors***, which represent only a percentage of the errors in the total testing process (TTP), which includes all pre-, intra-, and post-analytical phases.
- ◆ Other studies are based on methodologies, such as the split-specimen design, that are insensitive to some steps of the TTP.



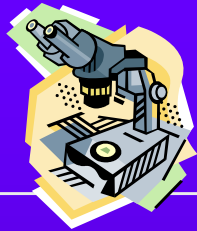
Laboratory errors in the Total Testing Process

Total errors patients involved: 363

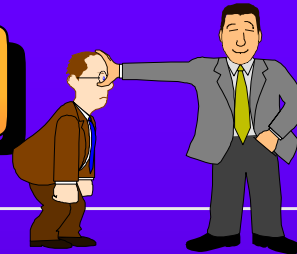
- Pre-analytical steps** 218 (45.5%)
- Analytical steps** 35 (7.3%)
- Post-analytical steps** 266 (47.2%)

Ross JW, Boone DJ, 1991

ERRORS IN LABORATORY MEDICINE:



ACTUAL LIMITATIONS (2)

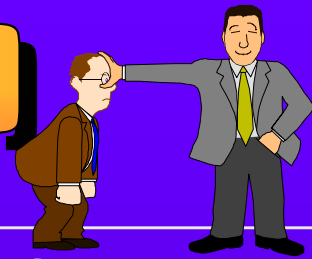


- ◆ Apart from a reluctance in reporting their own errors, it is extremely difficult for laboratories to identify all errors because ***many errors will neither produce detectable abnormal results nor raise questions for the user.***

ERRORS IN LABORATORY MEDICINE:



ACTUAL LIMITATIONS (3)



- ◆ The reported errors are only the tip of the iceberg because, as stated by Goldschmidt,
- ◆ a) 75% of errors produce results within the reference intervals.
- ◆ b) 12.5% produce wrong results that are so absurd that they are not considered clinically
- ◆ C) the remaining 12.5% of errors may have effect on patient health.



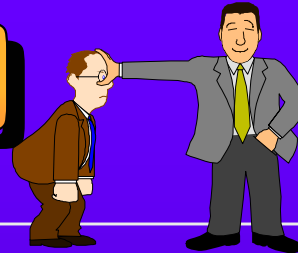
Blunders affecting patient results which are within “normal” limits are particularly difficult to detect by both laboratory personnel and clinicians



ERRORS IN LABORATORY MEDICINE:



ACTUAL LIMITATIONS (4)



- ◆ The new pathophysiologic insights and the development of highly specific and sensitive laboratory tests have changed the ***relationship between laboratory information and the gold standards.***



Error rates in clinical laboratories



One identified error every

33-50 events

50-100 events

330 events

1000 events

2237 events

8300 laboratory results or

2000 patients

900 patients

214 laboratory results

164 laboratory reports

283 laboratory results

McSwiney and Woodrow ('69)

Souverein et al. ('80)

Chambers et al. ('86)

Boone ('90)

Witte et al. ('97)

Lapworth and Teal ('94)

Nutting et al. ('96)

Plebani and Carraro ('97)

Stahl et al. ('98)

Hofgartner and Tait ('99)



Review of the literature on laboratory errors

Sector of the laboratory	Lapworth and Teal (10) <i>Clinical chemistry</i>	Goldschmidt and Lent (7) <i>Whole laboratory</i>	Nutting et al. (36) <i>Primary care</i>	Plebani and Carraro (8) <i>Stat laboratory</i>	Stahl et al. (37) <i>Whole laboratory</i>
Data collection period	1 year	6 years	6 months	3 months	3 years
No. of test	~997 000	Nd ^a	ND	40 490	676 564 ^b
No. of patients	~249 000	ND	160 714	ND	ND
No. of errors	120	133	180	189	4135 ^b
Frequency	0.05% of patients		0.11% of patients	0.47% of test results	0.61% ^b of test results
Preanalytical phase	31.6%	53%	55.6%	68.2	75%
Analytical phase	31.6%	23%	13.3% overall (4.4% if referral laboratory; 40% if POCT)	13.3%	16% ^b
Postanalytical phase	30.8%	24%	30%	18.5%	9% ^b
Multiple phases	6%				
Identification errors	41 (34%)	77 (58%)	ND	5 (2.6%)	ND



ERRORS in the PRE-ANALYTIC PHASE

- ◆ It is possible, even probable, that the most frequent ***pre-analytical errors are represented by an inappropriate choice of laboratory tests*** or panel of tests, and that most post-analytical errors derive from ***inappropriate interpretation and utilization*** of laboratory results.

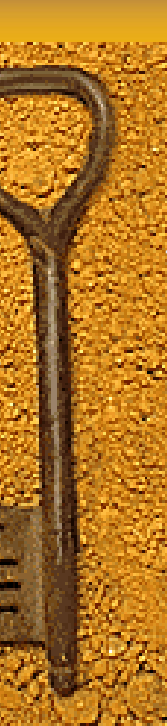


A CAP Q-Probes Study



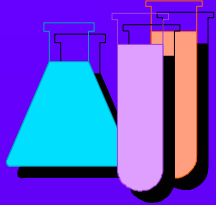
of Requisition Order Entry Accuracy

	N ^o	%
• Total test requisitions examined	114,934	
• Total order entry errors	5,514	4.8
• Test(s) ordered but not performed	1,658	1.4
• Test(s) performed but not ordered	1,221	1.1
• Physician name discrepancies	2,130	1.9
• Test priority errors	934	0.8



Types of preanalytical errors registered during the year 2000 at the Laboratory of San Raffaele Hospital

Type of error	No. Of missing results	
	Inpatients	Outpatients
Hemolyzed sample	8494	256
Insufficient sample	3256	102
Incorrect sample	1824	289
Clotted sample	792	80
Incorrect identification	287	2
Lack of signature (blood group)	266	-
Empty tube	238	8
Lack or wrong compilation of the accompanying module	120	-
Sample not on ice	75	6
Tube broken in the centrifuge	57	36
Test not reserved	31	-
Urine not acidified	24	-
Open container	20	13
Module without signature	14	-
Urine volume not indicate	5	-
Total	15 503	792



Laboratory errors in the CAP Q-Probe of blood bank practices

<i>Total errors</i>	<i>64,000</i>
• Pre-analytical steps	52%
• Analytical steps	5%
• Post-analytical steps	43%

Bachner P, Boone DJ, et al., 1991



Has the unacceptable result rate improved over time?

- ◆ Belk and Sunderman (1947)
- ◆ College of American Pathologists (1996)
- ◆ Plebani and Carraro (1997)
- ◆ Witte D.L. et al. (1997)
 - (“pure” analytical errors)

ppm

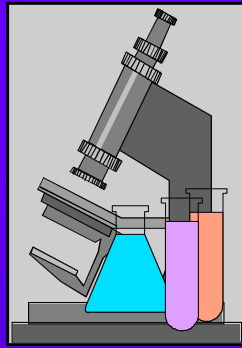
162,116

12,904

4,700

447

Mistakes and patient outcomes



J.W. Ross and
D.J.Boone

P.A.Nutting et al.

M. Plebani, P. Carraro

Number

336

180

189

***Effecton
patient care
[%]***

30

27


26

***Risk of
inappropriate
care
[%]***

7

12

6.4



Overall rates of unsatisfactory and unsuccessful performance

<i>Facility type</i>	<i>Total analyte challenges</i>	<i>Unsatisfactory % (n°)</i>	<i>Unsuccessful % (n°)</i>
● Physicians'office laboratories	656	21.5 (141)	4.4 (29)
● Physicians'office laboratories using medical technologists	662	14.0 (93)	1.8 (12)
● Non-physicians'office laboratories	2991	8.1 (243)	0.9 (26)

Hurst J., JAMA 1998;279:468-71.



Odds ratio of unsatisfactory proficiency testing event performance

(all other testing sites *vs* hospital and independent laboratories)

Analyte

***Odds ratio confidence
(95% interval)***

• ***All analytes***

2.89

• ***Potassium***

7.51 (6.59-8.54)

• ***Theophylline***

5.5 (4.64-6.64)

• ***Hemoglobin***

4.56 (4.08-5.09)

• ***Uric acid***

4.32 (3.78-4.94)

• ***Total bilirubin***

4.28 (3.78-4.85)

Stull TM et al., JAMA 1998;279:463-7.



ERRORS IN LABORATORY MEDICINE: TENTATIVE CLASSIFICATION

In order to identify the most critical steps in the TTP and to set up a plan for a corrective strategy we have to make a distinction between:



- a) Errors ***exclusively inside the laboratory.***
- b) Laboratory errors caused by organizational ***problems outside the laboratory.***
- c) ***Errors at the laboratory-clinical interface.***



ERRORS IN LABORATORY MEDICINE: TENTATIVE CLASSIFICATION

Errors exclusively inside the laboratory:

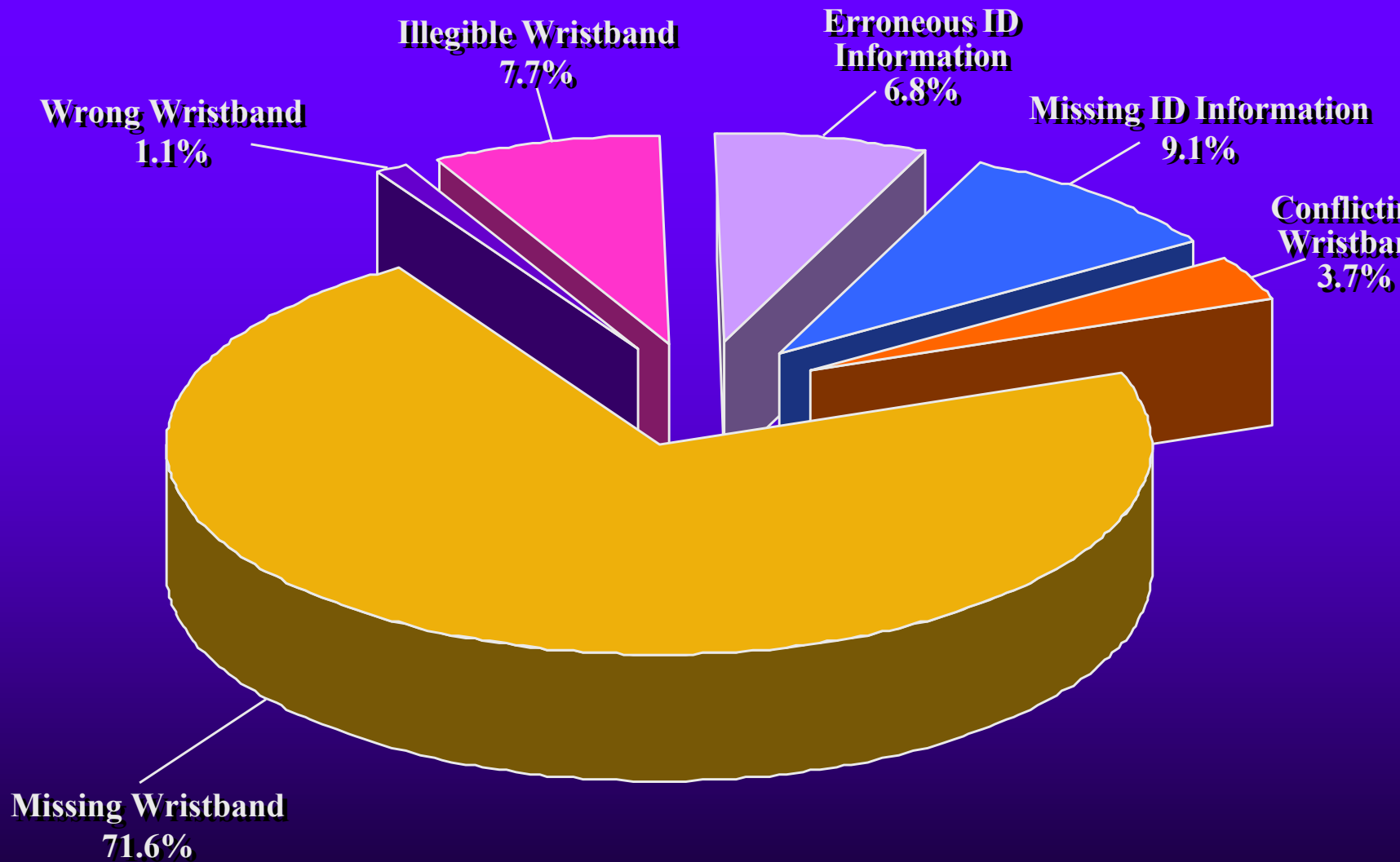
- ◆ Analytical errors
- ◆ Acceptance of improper specimens
- ◆ Sample mismatch during the analysis
- ◆ Undue increase in TAT
- ◆ Mistakes or failures in reporting



ERRORS IN LABORATORY MEDICINE: TENTATIVE CLASSIFICATION

- ◆ Laboratory errors caused by organizational problems outside the laboratory should be defined
“patient investigation errors”
- ◆ (e.g. sample-patient mismatch during the blood withdrawal performed by nonlaboratory personnel).

TYPES of WRISTBAND ERRORS





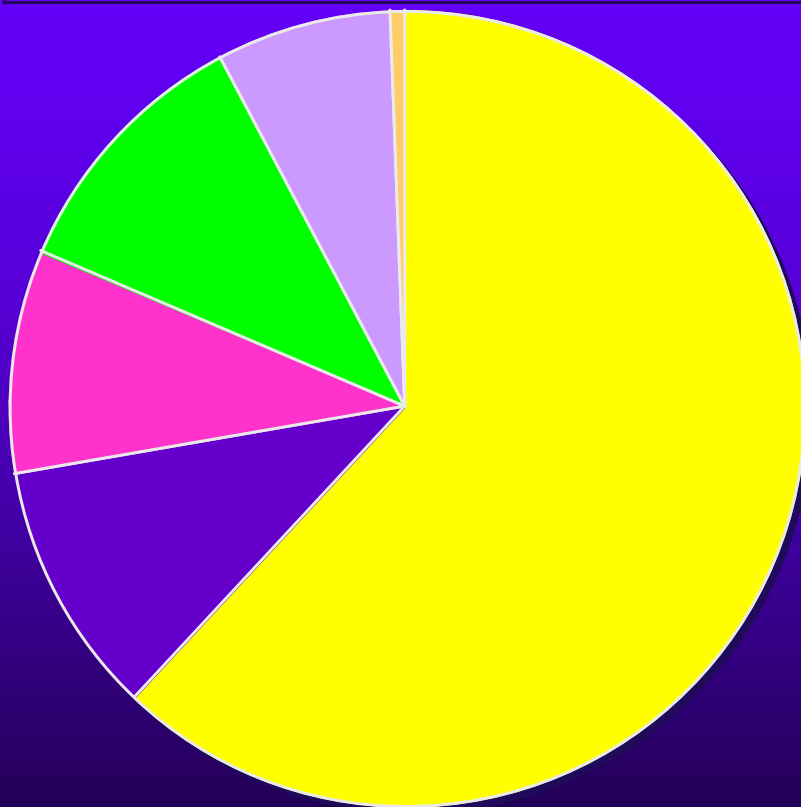
WRISTBAND ERROR RATES (%)

- CAP Q-TRACKS STUDIES -

- ◆ **1991** **5.5** **(10% of participants with error rates $\geq 10.9\%$)**
- ◆ **1993** **8.4** **(hospitals with fewer than 200 beds)**
- ◆ **1995** **7.4**
- ◆ **1999 *first quarter*** **7.4**
- ◆ **1999 *eight quarter*** **3.05**

The Laboratory Can Reduce Patient Identification Errors

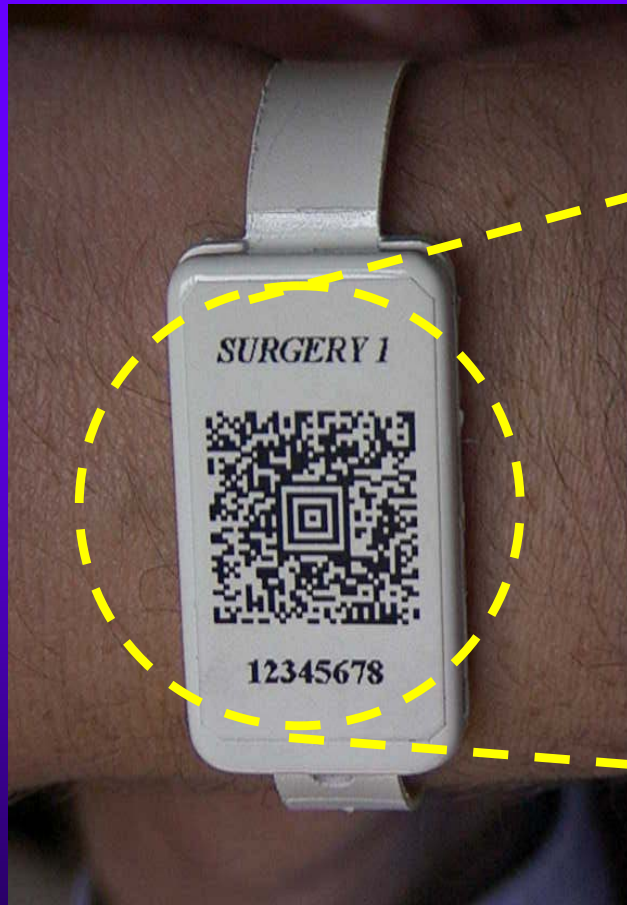
■ Missing ID	□ Differing ID	■ Incomplete ID
■ Wrong Data	■ Illegible	■ Wrong Patient



- ◆ Phlebotomy staff can monitor
- ◆ Interventions can reduce discrepancies
- ◆ Reduced discrepancies reduces disasters

Arch Pathol Lab Med
1993;117:573-577

IDENTIFICATION OF THE PATIENT



BOND
JAMES
dd/mm/yy
M
RAF007
123456789012
990088776655
card antib aspir

Applicazione protetta da brevetto

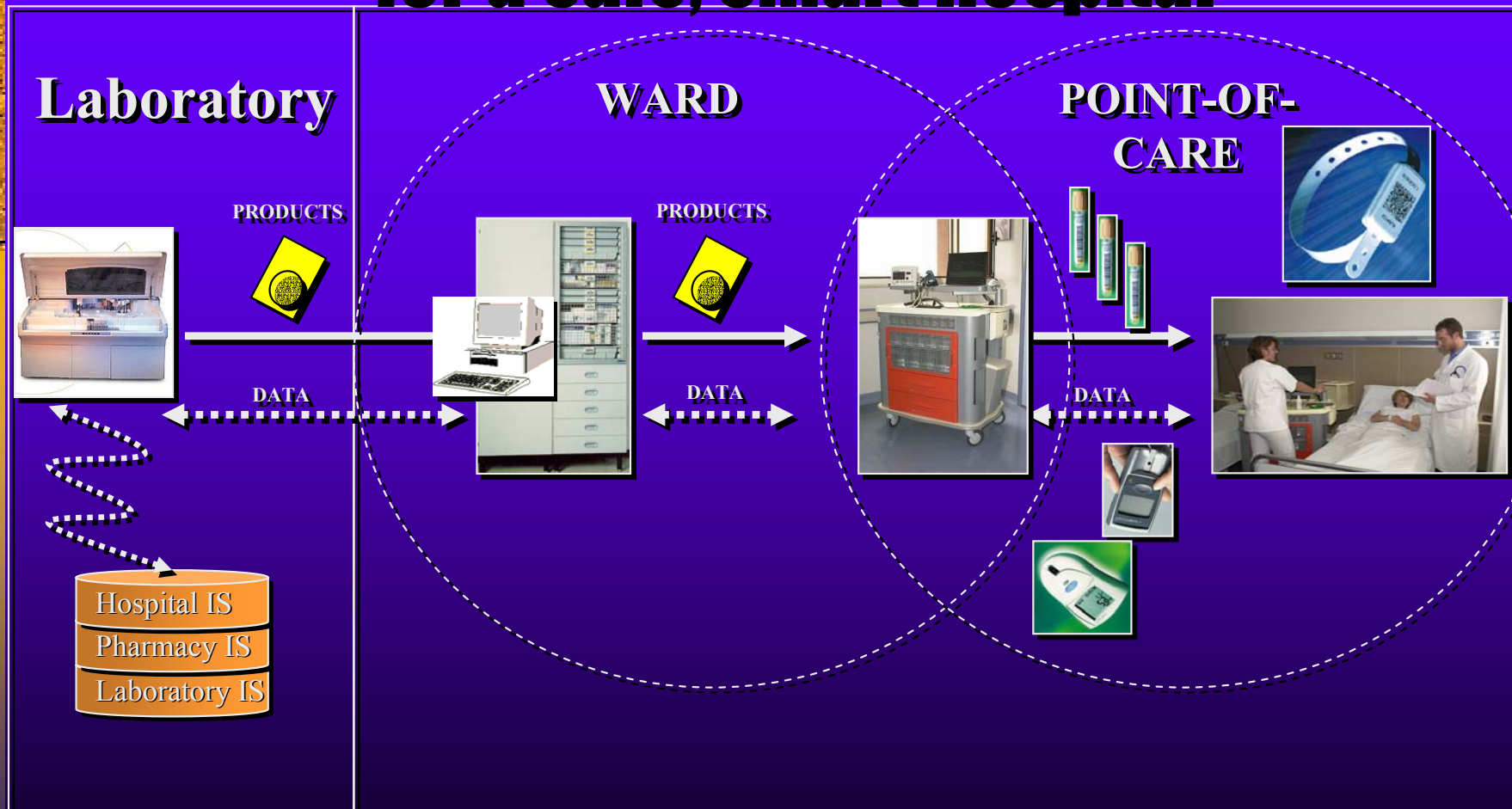


DRIVE - Drug in Virtual Enterprise

DRIVE APPROACH



- for a safe, smart Hospital -




Applicazione protetta da brevetto



ERRORS IN LABORATORY MEDICINE: TENTATIVE CLASSIFICATION

Errors at the laboratory-clinical interface:

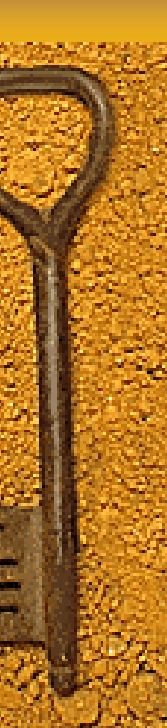
- ◆ Appropriateness in ***test request***.
- ◆ Appropriateness in ***test interpretation***.
- ◆ Appropriateness in ***test utilization***.



PHYSICIAN SURVEY ON CBC/DIFF REPORTS: STUDY RATIONALE

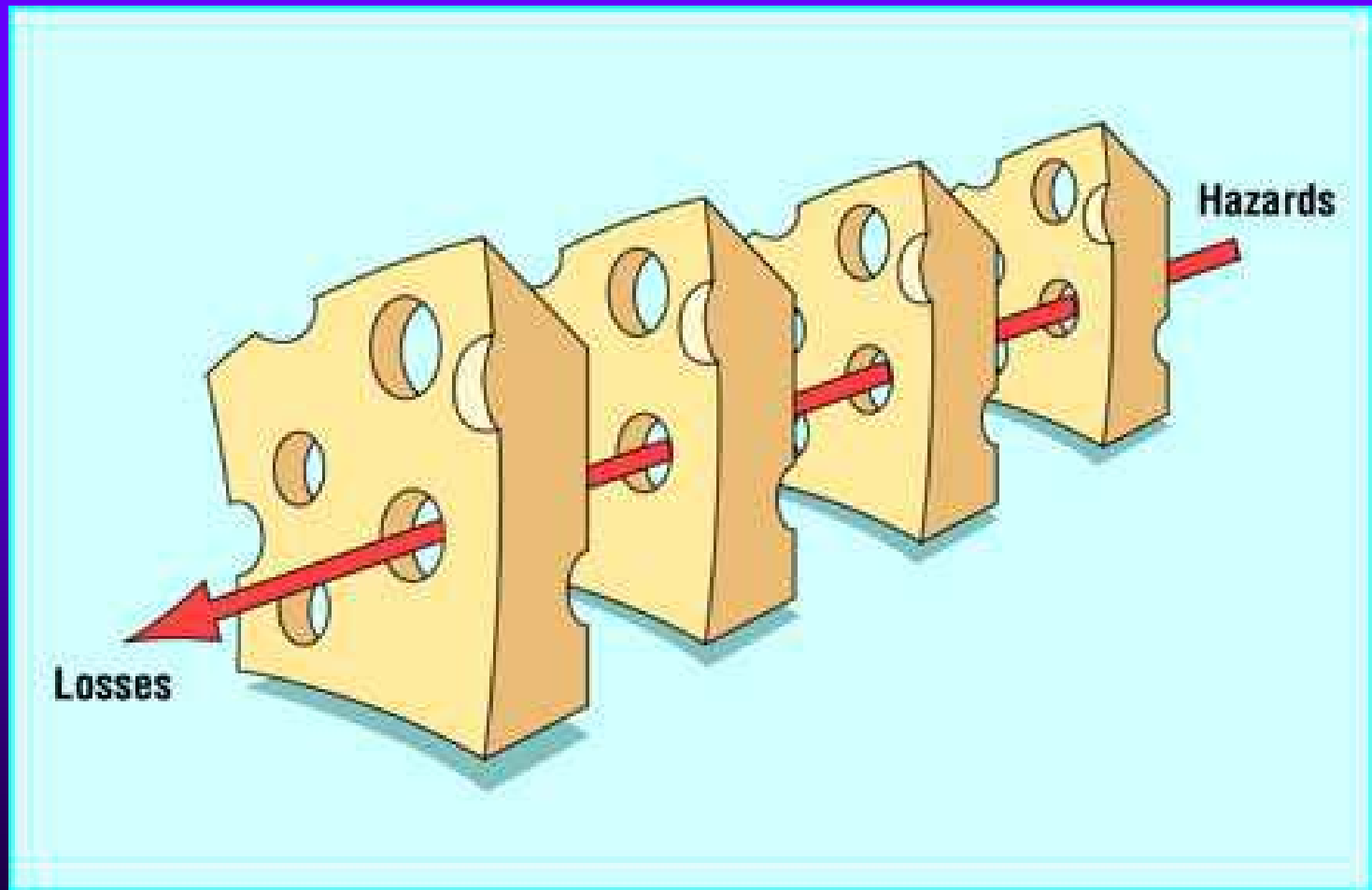
- ◆ CBC/Diff reports have become increasingly long and complex.
- ◆ Unnecessary information provided to clinicians may impede their comprehension of essential results.
- ◆ Simplification of reports might improve comprehension of the results and thereby reduce the potential for medical errors.

Linda M Sandhau, AACCC 200



The CBC has become a monster!

Errors Occur When All Defenses Fail



Background

- Organizational Risk -

HAZARDS

MISTAKES AND SLIPS:

- Errors of individuals
- Violations
- Diagnostic mishap

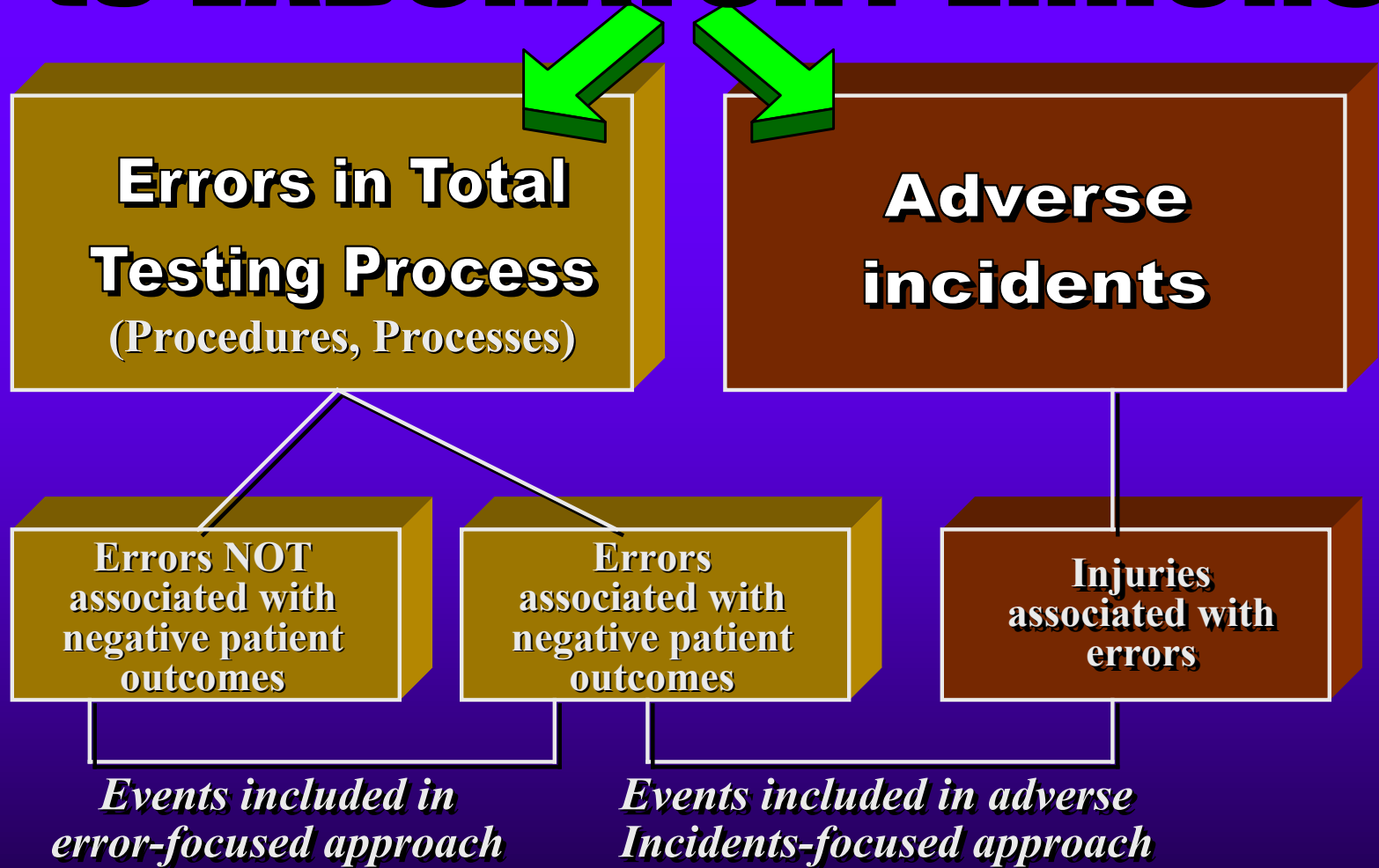
ORGANIZATIONAL FAILURES:

- Procedures/Processes
- Cultural constraints
- Legal and regulatory rules
- Failures in communications

Injuries and adverse incidents



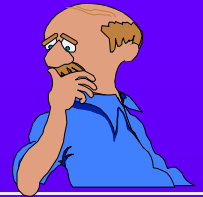
APPROACHES **to LABORATORY ERRORS**





ERRORS IN LABORATORY MEDICINE:

what should we do?



- ◆ There is a need for better definition of laboratory errors and their causes
- ◆ In fact, we can agree that laboratory error may be defined as ***“any defect from ordering tests to reporting results and appropriately interpreting and reacting on these”***

but



ERRORS IN LABORATORY MEDICINE:

what should we do?

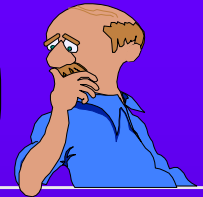


- ◆ It is important to classify laboratory errors by relating them to their real or potential effects on patient outcomes, allowing definition of the relevance of the error itself.
- ◆ (e.g. a hemolyzed sample is probably less problematic than sample mismatching or a TAT too long in a critical situation).



ERRORS IN LABORATORY MEDICINE:

what should we do?

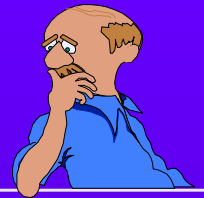


- ◆ A standard for laboratory error detection and reporting needs to be defined, and an accurate analysis of the risk of errors in the clinical laboratory needs to be performed.



ERRORS IN LABORATORY MEDICINE:

what should we do?

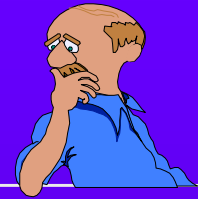


- ◆ It is important to define ways to decrease laboratory errors and to possibly avoid completely those with a real or potentially significant negative effect on a patient's health.



ERRORS IN LABORATORY MEDICINE:

what should we do?

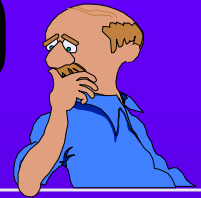


- ◆ An appropriate error detection program and adequate measures for error reduction that quantify the effects of these measures and evaluate whether the reduction can be considered satisfactory are critical.



ERRORS IN LABORATORY MEDICINE:

what should we do?



- ◆ Another fundamental step is to create a culture in which the existence of risk is acknowledged and injury prevention is recognized as everyone's responsibility.



Partners In Patient Safety



***Scientific Societies
Laboratory Professionals
Clinicians
Patients
Public***

***ERRORS REDUCTION MUST BEGIN AND END
WITH RELATIONSHIPS***

McNutt RA et al., JAMA 2002;287:1997-2001